REMARKS

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 1, 2, 4 and 7-24 are pending in this application. Claim 8 is amended and no claims have been cancelled or added. Claim 1 is the sole independent claim.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O. Action, summary at 12.

Claim Objections

Claim 1 has been objected to for formalities. The Examiner stated that polyethylene oxide and polyethylene glycol are the same compound. Applicants respectfully disagree.

Although the monomeric unit of polyethylene oxide and polyethylene glycol may be the same, Applicants submit that the resulting polymers, or copolymers, composed of these monomeric units are not regarded as the same in the art. Poly(ethylene glycol) (PEG), also known as poly(ethylene oxide) (PEO) or polyoxyethylene (POE), refer to an oligomer or polymer of ethylene oxide. In the art, PEG tends to refer to oligomers and polymers with a molecular mass below 20,000 g/mol, PEO to polymers with a molecular mass above 20,000 g/mol, and POE to a polymer of any molecular mass.

Therefore, withdrawal of the objection to claim 1 is respectfully requested.

Example Embodiments of the Present Application

Independent claim 1 recites a method comprising forming homopolymers or copolymers of TMC; molding said polymers formed into a desired shape; and irradiating said molded shape with actinic radiation in an inert atmosphere. As is illustrated in on page 14, table 3 and page 15, table 4 of the present application, irradiating the polymers in an air atmosphere does not allow for desirable properties. For example, table 4 clearly shows that the plateau creep rate of air irradiated samples is undesirable compared to the non-irradiated samples. On page 7, lines 20-31, of the application, the creep rate is an important factor in determining the suitability of the present polymeric structures.

Furthermore, when irradiated, the TMC-polymers of example embodimentsshow a net increase in crosslinking (see paragraph 50) thereby providing structures with **increased** mechanical properties. For example, see table 3 of example 2 showing an increased modulus and yield stress and table 4 of example 1 showing a decreased creep rate for TMC structures irradiated in an inert atmosphere.

Rejections under 35 U.S.C. § 103

Ritter in view of Schappacher, Gross, Wang and Zhu

Claims 1-2, 4, and 7-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,496,446 to Ritter et al. ("Ritter") in view of Biomaterials, 2001, by Schappacher et al. ("Schappacher"), U.S. Patent No. 6,093,792 to Gross et al. ("Gross"), J. of Poly. Sci., part A, 1998, by Wang et al. ("Wang") and Macromol, 1991 by Zhu et al. ("Zhu"). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Ritter teaches irradiating structural surgical elements with gamma radiation to improve properties such as initial strength, in vivo strength and degradation loss of said strength properties; that said surgical elements are made of bioabsorbable polymers, such as polyglycolides and copolymers of glycolides with trimethylene carbonate; that Ritter discloses the use of gamma radiation dosages of up to 10 Mrad; that, in addition, Ritter teaches ethylene glycol sterilization of said structural surgical devices; that Ritter fails to teach homopolymers of TMC and copolymers of TMC with polyethylene oxide, polyethylene glycol and caprolactone; that, however, homopolymers and copolymers of TMC with PEO, PEG and caprolactone for use in biomedical applications are known as can be evidenced by Schappacher, Gross, Wang, Sodergard and Zhu; that Schappacher sets forth homo- and co-polymers of TMC with e-caprolactone as biomedical nerve guides; that Gross sets forth copolymers of TMC with other lactones, such as e-caprolactone as bioresorbable copolymers for use in biomedical applications; that Wang sets forth copolymers of TMC with polyethylene glycol which can be used in

biomedical applications, such as sutures; that Zhu sets forth homopolymers of biodegradable TMC; that none of the secondary references teach the use of gamma radiation crosslinking, however, the Examiner deems that it is well within the skill level or an ordinarily skilled artisan to use the method of Ritter, that is exposing biodegradable polymers comprising TMC to improve the mechanical properties, to improve on other known copolymers of TMC, such as those taught by the secondary references, to improve the mechanical properties; that the rationale being that it is obvious to apply a known technique, in this case crosslinking bioabsorbable copolymer of TMC via radiation to improve mechanical properties, to a known product, in this case copolymer of TMC for biomedical usages to yield predictable results; and that at the very least the Examiner deems that it would have been at least "obvious to try" crosslinking other copolymers. Applicants respectfully disagree.

Applicants respectfully submit that the Examiner has failed to point out each and every element of independent claim 1 disclosed by Ritter, Schappacher, Gross, Wang and Zhu. Therefore, Applicants request that the next Office Action be made non-final.

In addition, the Examiner does not point out (nor can the Applicants find) where any of the cited references Ritter, Schappacher, Gross, Wang and Zhu teach or suggest "irradiating said desired shape with actinic radiation in **an inert atmosphere** for crosslinking" as recited in claim 1. Rather, in example 7 of Ritter, the copolymer may be irradiated (sterilized) in an air atmosphere (column 8, lines 4-11), rather than an inert atmosphere as recited in claim 1.

Further, the Examiner asserts that Ritter discloses irradiating structural surgical elements with gamma irradiation to improve their properties such as strength. However, Applicants respectfully submit that the structural surgical elements according to Ritter are already formed and ready to use elements. Inherently, the ready to use structural surgical elements according to Ritter already comprise crosslinks that provide a stable form. In the case of glycolide based polymers, crosslinking predominately comprises physical crosslinking, i.e., inter and intra molecular interactions of the polymer chains not involving covalent bonds between these chains, thereby providing a stable structure. In case of the TMC based polymers as recited in claim 1, such physical crosslinking is substantially absent and, accordingly, in the absence of (chemical) crosslinking, i.e., the formation of covalent bonds, the polymer composition does not have a stable form. Thus, the gamma irradiation disclosed in Ritter is not used to provide a shaped biodegradable elastomeric structure as is presently recited in claim 1, but is used to further modify the properties of an already shaped biodegradable structure (see abstract and example 6 of Ritter). As such, Ritter also does not disclose forming a polymer composition in a desired shape, as is recited in claim 1, simply because the structures of Ritter are already in a desired shape. Further, Ritter does not disclose irradiating the desired shape as recited in claim 1, much less in an inert atmosphere, in order to crosslink, i.e., stabilize, the desired shape and thereby providing the present shaped biodegradable elastomeric structures. (See paragraphs 13 and 14 of the present application explicitly reciting that the actinic radiation is used to obtain a stable shaped structure).

Additionally, column 2, lines 23-29 of Ritter explicitly limit their discovery to bioabsorbable materials having a glycolic ester linkage, a linkage which cannot be found in the biodegradable elastomeric structures according to claim 1. As such, the assertion of the Examiner that Ritter discloses improving properties such as strength appears not to be warranted. As is already clear from the abstract, Ritter discloses controlling, and not improving, the rate of strength loss and degradation by irradiation. Strength loss is identified in Roby et al. as a problem associated with Ritter (column 1, lines 28-31).

Even if one would accept the argument of the Examiner that Ritter discloses improving mechanical properties through radiation, Ritter teaches away from the subsequent extrapolation of the reported results to other types of polymers, as appears to be suggested by the Examiner. Reference is made to c9, last lines, explicitly stating: *"The most satisfactory means for in vivo strength retention....These results are surprising and* ***unpredictable*** *since it is known that polyglycolic acid* ***differs in its response to radiation from other polymers***".

Therefore, as Ritter only discloses further irradiating already existing – inherently (physically) crosslinked -medical structures comprising glycolic ester linkages in order to modify their properties, and appears to explicitly limit the disclosure to glycolic polymers, the combination of Ritter, Schappacher, Gross, Wang and Zhu cannot render at least claim 1 obvious.

The Applicants, therefore, respectfully request that the rejection to independent Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2, 4 and 7-24, dependent, directly or indirectly, on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

Roby in view of Schappacher, Gross, Wang and Zhu

Claims 1-2, 4, 7-21 and 23-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,889,075 to Roby et al. ("Roby") in view of Schappacher, Gross, Wang and Zhu. Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Roby sets forth irradiated surgical sutures and methods of making them; that said surgical sutures are fabricated from a copolymer of dioxanone, trimethylene carbonate, and glycolide, which is treated with gamma irradiation to enhance the properties; that said copolymers can be arranged in sequences as found in column 2, lines 59-68 to column 3, lines 1-14; that the irradiation treatment is from a total dose rate from about 2 to about 12 Mrad in an inert atmosphere while under vacuum; and that, thus, the Examiner deems claims 10 and 11 are envisioned in the reference.

Applicants respectfully submit that the Examiner has failed to point out each and every element of independent claim 1 disclosed by Roby, Schappacher, Gross, Wang and Zhu. Therefore, Applicants request that the next Office Action be made non-final.

Similarly to the discussion of Ritter above, Applicants submit that Roby discloses irradiating already formed satures, i.e., BIOSYN sutures. Additionally, with respect to the sutures obtained, Roby explicitly states: *These results show that irradiated sutures had an enhanced rate of absorption, but maintained acceptable initial strength (c4l54-56)"* and *"These results show that the irradiated sutures had an enhanced rate of absorption. However, the physical characteristics of the suture were not significantly adversely affected by irradiation (c5l22-25)"*. Please note that Tables I, II and III, in most cases, show that the irradiated sutures already had a 50% reduced breaking strength after 1 dose of radiation, an effect which Applicants respectfully submit can hardly be regarded as an improved property.

In fact, Roby discloses the chain scissioning effect which is reported in paragraph 18 of the present application. As is generally known in the art, irradiating a polymeric structure will result in more chain-scissioning than crosslinking resulting in a net reduction of the inter and intra molecular bonds, which increases the biodegradability of the structure but, simultaneously, reduces its mechanical strength. This effect is illustrated in Tables I to III of Roby reciting obtaining a controlled balance between bioabsorbance and **loss** of strength.

In contrast, the TMC-polymers recited in claim 1, when irradiated in an inert atmosphere, show unexpectedly (see paragraph 50 of the application) more (chemical) crosslinking than chain-scissioning, i.e., a breakage of the covalent bonds, resulting in an increased mechanical strength. Applicants further submit that irradiating the glycolide based polymers of Roby and Ritter

will result in net chain scissioning thereby making the structures disclosed more biodegradable, but inherently the mechanical strength is reduced. By controlling the actinic radiation, hence the chain-scissioning, both Roby and Ritter try to find a balance between a reduced mechanical strength and biodegradability.

Applicants submit that irradiation is used in Roby to reduced the number of intra and inter molecular bonds in a stable polymeric structure in order to **increase** the bioabsorption, but this inherently **decreases** the mechanical strength, which is experimentally detailed in Roby and to a lesser extent suggested in Ritter disclosing strength retention control (c3l17-18) and rate of strength loss (c2l26).

The Applicants, therefore, respectfully request that the rejection to Claim 1 under 35 U.S.C. § 103(a) be withdrawn.

Claims 2, 4, 7-21 and 23-24, dependent, directly or indirectly, on independent claim 1, are patentable for the reasons stated above with respect to claim 1 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 1 and all claims dependent thereon.

CONCLUSION

In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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